## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While the present specification discloses the amount of granisetron may be up to about 10% by weight (page 9 last paragraph bridging page 10), it appears that the present specification does not provide support for the limitation "the adhesive is loaded with between 3 and 12% w/w granisetron" in claim 23. However, because claims 23-25 are originally filed claims, the specification can be amended to incorporate these limitations.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is rejected in the use of the phrase "adapted to provide a pharmacologically effective amount of granisetron after about 2 hours". It is unclear what the phrase is referring to. Is it: 1) a device that does not release the drug until after 2 hours; or 2) a device that provides a $T_{max}$ and/or $C_{max}$ after 2 hours? Is there any drug release before the "2 hours"? What is "a pharmacologically effective amount of granisetron after about 2 hours"? Further clarification is requested.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26, 28-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Effing WO 98/53815 A1.

Effing teaches a transdermal drug delivery device or a pressure sensitive skin adhesive device comprising an adhesive layer containing: 1) a copolymer of one or more A monomers and one or more B monomers, and 2) a therapeutically effective amount of granisetron as an active agent (abstract; page 2, lines 14-28; and claims 1 & 11). A monomers include n-butyl, and 2-ethylhexyl acrylates or methacrylates (page 4, 2nd paragraph; and claim 10). Active agent presents in the device ranges from 4-15% (page 5, lines 28-29). Effing further teaches the device has a surface area of about 15 $cm^2$ to about 60 $cm^2$ (page 7, lines 20-22). The device comprising granisetron is useful

for the treatment of emesis and/or nausea during chemotherapy (abstract; page 1, lines 23-27; page 3, lines 1-5; and page 7, lines 23-29). The device shows stability at storage conditions under 25°C and 40°C after 4 weeks (examples 1 & 2).

It is noted that Effing does not explicitly teaches the property of the device, such as effective amount of granisetron after 2 hours. However, such limitation is inherent because Effing teaches the use of the same materials for the same active agent, namely, a transdermal patch comprising granisetron loaded into an adhesive made of n-butyl, and 2-ethylhexyl acrylates or methacrylates. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim 22 is rejected under this section because it is a composition claim. The limitation "for the treatment and/or prophylaxis of a condition" is directed to future intended use, and the prior art structure is capable of performing the intended use as recited in the preamble, therefore it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). In the present case, Effing teaches the same transdermal patch for the same purpose, namely, transdermal patch of granisetron useful for the treatment of nausea and vomiting.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Effing WO 98/53815 A1, in view of Sanger et al. WO 94/01095 A2.

Effing is relied upon for the reason stated above. Effing does not teach using granisetron for the treatment of condition recited in claim 32.

Sanger teaches the use of 5-$HT_3$ receptor antagonist for the treatment of visceral pain and migraine (abstract). 5-$HT_3$ receptor antagonist includes granisetron (claim 8). Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of Effing for the treatment of migraine to obtain the claimed invention. This is because Sanger teaches using granisetron for the treatment of migraine and visceral pain is well known in the art.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1618